Remarks

The amendments and foregoing remarks are responsive to the June 22, 2005 Final Office Action. Applicants respectfully request reconsideration.

Status of the Claims

Claims 1 and 16 are amended. Claim 2 was cancelled previously. Claims 1 and 3-16 are pending.

Support for Amendments to the Claims

Support for the amendments to Claim 1 and 16 is found in the specification on page 12, line 20 to page 13, line 12. No new matter is added.

Rejection under 35 U.S.C. § 102(e)

In the Action, the Examiner maintained the rejection of Claims 1, 3-5 and 14-15 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,780,056 (Akamatsu) as evidenced by U.S. Patent No. 5,004,756 (Ogawa) for reasons of record.

The Examiner further alleges (with regard to Claim 1) that the product-by-process clause of Claim 2 is not given patentable weight because the claim is drawn to a composition. Claim 1 as amended herein should now be given patentable weight, as the patentability of the composition does not depend on a method of production.

According to an aspect of the invention, a carotenoid composition comprising lycopene suspended or dispersed in a medium-chain length triglyceride derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol which maintains the concentration of lycopene for at least three months at 25°C is provided.

Although the use of standard soybean oil extracted using solvents has proved effective for preventing oxidation of carotenoids such as β-carotene, it has not

prevented commercially significant degradation of lycopene, which is one of the most readily oxidized carotenoids. Advantageously, Applicants have found that medium chain triglycerides derived from the esterification of substantially pure glycerol and fatty acids, rather than natural source oils extracted with solvents, reduces the presence of impurities that may cause or induce oxidation of the carotenoid. *See*, p. 3, lines 4-11 and 14-18 and p. 5, lines 3-11 of the specification.

The Akamatsu patent relates to microcapsules with a multi-core structure containing natural carotenoid and an edible oil. The microcapsules prevent oxidation of the carotenoids. *See*, col. 6, lines 10-15 of Akamatsu. Natural carotenoid may include palm oil, donariera algae, carrot, alfalfa, corn and tomato. "Donariera" algae presumably is misspelled and corresponds to "dunaliella" algae which contains a mixture of carotenoids (predominantly β-carotene) and may or may not include lycopene. Edible oils include peanut, soybean, cotton seed and corn. Medium chain length triglycerides (synthetic MCT) are also listed. In Example 7, the carotenoid used is donariera algae and the edible oil is MCT. As illustrated in Table 2 (col. 11), only ninety-one percent of the carotenoid derived from donariera algae is present in the microcapsule form after two months storage at 40°C.

The Ogawa patent relates to a pharmaceutical oil-in-water type microemulsion comprising fine particles of a vegetable oil or triglyceride of a medium-chain (C_{8-12}) fatty acid (such as caprylic acid, capric acid and lauric acid), normally abbreviated as MCT, containing N-solanesyl-N-N'-bis(3,4-dimethoxybenzyl)ethylenediamine malate, an aqueous medium, and a phospholipid. In Example 5, the malate compound is added to soybean oil (C_{16-18}) and MCT (mixture) to which is added purified soybean phospholipids, purified yolk phospholipids and glycerol.

Applicants respectfully submit that the subject matter of Claim 1 is not identically disclosed by Akamatsu. Although Akamatsu discloses lycopene as a carotenoid and MCT as a triglyceride, there is no disclosure whatsoever of a medium-chain length

triglyceride derived from esterification of a substantially pure medium chain fatty acid and substantially pure glycerol which maintains the concentration of lycopene for at least three months at 25°C. Instead, Akamatsu discloses that it is solely the microcapsules which prevent oxidation.

In addition, none of the Examples of Akamatsu specifically exemplifies the use of lycopene. Presuming, *arguendo*, that donariera (donaliella) algae is a source of lycopene, Table 2 (for Example 7) illustrates that the concentration of the carotenoid (contained in microcapsule form) decreased over a period of two months at 40°C, whereas the concentration of lycopene in Claim 1 was maintained for at least three months at 25°C.

On page 7, line 19 of the Action, the Examiner alleges that the medium chain fatty acid of Akamatsu is the "very same component" as Applicants' triglygeride. Applicants respectfully disagree. Applicants' medium-chain triglyceride (obtained by esterification of a substantially pure fatty acid and glycerol) maintains the concentration of lycopene for at least three months at 25°C, whereas the microcapsules of Akamatsu prevent oxidation of the carotenoid contained therein. Therefore, the composition of Akamatsu is not the same as Applicants' composition.

The addition of Ogawa fails to cure the deficiencies of Akamatsu. Although Ogawa is cited by the Examiner as evidence that medium-chain length triglycerides have 8-12 carbon atoms, the disclosure in Ogawa of the carbon chain-length of the triglyceride fails to lead one skilled in the art to derive a triglyceride from esterification of a substantially pure fatty acid and glycerol or to achieve a triglyceride that maintains the concentration of lycopene for at least three months at 25°C as claimed.

Thus, in view of Akamatsu's disclosure that microcapsules prevent oxidation, and the lack of disclosure that a suspended or dispersed carotenoid in a triglyceride (or MCT) derived from esterification of a substantially pure fatty acid and glycerol will maintain the concentration of a carotenoid, specifically lycopene, for at least three

months at 25°C, Akamatsu does not anticipate the invention. The addition of Ogawa fails to cure the deficiencies of Akamatsu, and hence, the rejection should be withdrawn. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The Examiner maintained the rejection of Claims 6-13 and 16 under 35 U.S.C. § 103(a) as being unpatentable over Akamatsu. The arguments set forth above with regard to the rejection under 35 U.S.C. § 102(e) based on Akamatsu are reasserted as if set forth at length herein.

Akamatsu fails to disclose, teach or suggest the subject matter of Claims 6-13 and 16. Although Akamatsu discloses lycopene as a carotenoid and MCT as a triglyceride, Akamatsu does not teach or suggest a composition containing lycopene dispersed or suspended in a medium chain triglyceride derived from esterification of a substantially pure fatty acid and substantially pure glycerol which maintains the concentration of lycopene for at least three months at 25°C. In contrast, Akamatsu discloses that the microcapsules solely prevent oxidation.

In addition, none of the Examples of Akamatsu exemplify the use of lycopene. Although it is believed that the donariera algae (combined with MCT in Example 7) contains predominantly β-carotene, the actual content of carotenoids is not disclosed. The disclosure of Akamatsu thus fails to provide motivation to select lycopene and to obtain a triglyceride from esterification of a substantially pure fatty acid and glycerol to maintain the concentration of lycopene for at least three months at 25°C.

Therefore, in view of the lack of teaching, suggestion or motivation from Akamatsu, it would not have been obvious to administer Akamatsu's composition to a host to provide lycopene in a medium-chain triglyceride which maintains the concentration of lycopene for at least three months at 25°C, and the rejection should be

withdrawn. Reconsideration and withdrawal of the rejection are respectfully requested.

Petition for Extension of Time/Fees

A Petition for a One-month Extension of Time and requisite fee are enclosed. No additional fees are believed due. The Commissioner is authorized, however, to charge (or credit any balance) any fees deemed due (or owing) to Deposit Account No. 50-1177.

Conclusion

It is respectfully submitted that Claims 1 and 3-16 are in condition for allowance. A Notice of Allowance is respectfully requested. If anything further is needed to advance the allowance of this application, the Examiner is urged to contact Applicants' attorney at the telephone number indicated below.

Respectfully submitted,

Date: February 16, 2006

Jane E. Alexander
Attorney for Applicants
Registration No. 36,014
Telephone: (215) 628-1474
Facsimile: (215) 628-1345

Cognis Corporation
300 Brookside Avenue
Ambler, PA 19002

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